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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/765,652	01/26/2004	Gopal K. Chotani	GC707-C1	1202
75	590 08/29/2006 .		EXAM	INER
KAMRIM T. MACKNIGHT			UNDERDAHL, THANE E	
GENENCOR INTERNATIONAL, INC. 925 PAGE MILL ROAD			ART UNIT	PAPER NUMBER
	CA 94304-1013		1651	
			DATE MAILED: 08/29/200	

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)					
	10/765,652	CHOTANI ET AL.					
Office Action Summary	Examiner	Art Unit					
	Thane Underdahl	1651					
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply							
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).							
Status							
1) Responsive to communication(s) filed on 21 Ju	Responsive to communication(s) filed on 21 July 2006.						
· <u> </u>	action is non-final.						
· —	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is						
closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.							
Disposition of Claims							
4)⊠ Claim(s) <u>30-40,42 and 51-69</u> is/are pending in the application.							
4a) Of the above claim(s) <u>32-34,56,57,62 and 63</u> is/are withdrawn from consideration.							
5) Claim(s) is/are allowed.							
6)⊠ Claim(s) <u>30-31, 35-40, 42, 5155, 58-61, and 64-69</u> is/are rejected.							
7) Claim(s) is/are objected to.							
·	8) Claim(s) are subject to restriction and/or election requirement.						
Application Papers	·						
9) The specification is objected to by the Examiner.							
10)⊠ The drawing(s) filed on <u>1/26/2004</u> is/are: a)□ accepted or b)⊠ objected to by the Examiner.							
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).							
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.							
Priority under 35 U.S.C. § 119							
<ul> <li>12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) All b) Some * c) None of:</li> <li>1. Certified copies of the priority documents have been received.</li> <li>2. Certified copies of the priority documents have been received in Application No.</li> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>							
Attachment(s)							
Notice of References Cited (PTO-892)  4) Interview Summary (PTO-413)							
2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)	Paper No(s)/Mail Da 5) Notice of Informal Pa						
) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  Paper No(s)/Mail Date 8/2/2004.  5) Notice of Informal Patent Application (PTO-152)  6) Other:							
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#### **DETAILED ACTION**

#### Election/Restrictions

1. Applicant's election without traverse of claims 30-40, 42 and 51-69 in the reply filed on 7/21/06 is acknowledged. The species election of an: intermediate product-glucose, substrate converting enzyme—cellulase, and an end product—1,3-propanediol is also acknowledged. In the same reply the applicant cancelled claims 1-29, 41, and 43-50 and added new claims 61-69.

2. However claims 32-34, 56, 57, 62, and 63 are withdrawn as not being directed to the elected species. (see M.P.E.P. § 821.03)

## **Drawings**

3. The drawings are objected to because they do not have the proper margin size of 2.5 cm (1 inch). Please see M.P.E.P. § 608.02 V(g). Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each

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drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

## Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- 5. Claims 30-31, 35-40, 42, 51, 53-55, 58-61, and 66-69 are rejected under 35 U.S.C. 102(b) as being anticipated by Haynie et al. in light of Richard (Cornell Waste Management Institute, 1996), Lee (Metabilic Engineering, 1999), and Allcock et al. (Applied Environmental Microbiology, 1981).
- 6. All the claims listed above are drawn to a method of producing 1,3-propanediol (1,3-PD) via a 2 step process. The first step produces an intermediate comprising glucose as a product from the cellulose substrate via cellulases and then the second step converts glucose to and end product, specifically 1,3-PD, via recombinant microorganisms such as *E. coli*.
- 7. Haynie et al. teach converting cellulose containing materials such as corn steep liquor or barley malt into glucose using cellulase excreted by microorganisms which will

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further be used to produce glycerol and 1,3-PD as and end-product, which is isolated (anticipates claims 30, 31, 51, 53, 55, 59) (please see Abstract, page 2 lines 20-35 and Page 9, line 27-38).

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- 8. Lee et al. teach that cellulases are inherently produced and secreted by yeasts such as S. cerevisiae for the purpose of cellulose hydrolysis to glucose (page 287, Cellulose). S. cerevisiae (page 6, line 19) is used by Haynie et al. to convert cellulose to glucose and then ferment the glucose to glycerol which in turn is fermented to 1,3-PD (anticipates claim 35).
- 9. Barley malt inherently contains both lignin and cellulose, so is considered a lignocellulosic material as supported by Richard et al. (Cornell Waste Management Institute).
- 10. The applicant also claims the intermediate converting enzyme is a microbial enzyme, more specifically a bacterium which is a recombinant E. Coli strain (anticipates claims 30, 51, 54, 67, 68). Haynie et al. teach that an intermediate comprising glucose can be converted to glycerol which in turn can be converted to 1, 3-PD via a recombinant E. Coli strain at a pH between 5 and 8 for 24 to 48 hours (Page 2, lines 19-25. page 6, lines 14-28, and Page 7, lines 6-11, page 7, line 10, page 16 line 38)
- 11. The applicant claims the intermediate composed of glucose is converted by a microbial enzyme that is secreted by a microorganism in contact with the intermediate (anticipates claims 35, 36). Haynie et al. teach Strains of Clostidium, which is used by Haynie, secrete cellobiase which hydrolyzes cellobiose (a glucose comprising

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intermediate (Page 6 line 19). The production of strains of cellbiase secreting Clostidium are supported by Allcock et al. (page 539, 2<sup>nd</sup> column, last paragraph).

- 12. The applicant claims reducing catabolic and enzymatic inhibition of the method (anticipates claims 37, 38, 39, 40, 60). Haynie et al. teach overcoming "the difficulties of catabolite repression, feedback inhibition and carbon sources diversion to create a system that is optimized for 1,3-propanediol production" (Page 3, line 29-32).
- 13. The applicant claims the production and isolation of an end-product, specifically 1,3-PD (anticipates claims 30, 42, 55, 58, 61, 66). Haynie et al. teach using a mixed yeast and bacterial cultures supported on the same carbon source, they were able to produce and isolate an end-product specifically 1,3-PD (Abstract).
- 14. The applicant claims the production of an intermediate product glucose via cellulases and the conversion of glucose by an intermediate-converting microbe or microbial enzyme (anticipates claims 30, 51, 53). Haynie et al. teach the method can use cellulose. Cellulose is inherently broken down by cellulases to glucose by recombinant yeasts such as S. cerevisiae (as supported by Lee et al, page 287) which in turn can be converted to glycerol (Page 9 line 30, and page 2 line 23).

# Claim Rejections - 35 USC § 103

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

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16. Claims 52, is rejected under 35 U.S.C. 103(a) as being unpatentable over Haynie et al. as applied to the claims above (see paragraph 4) and in view of Chang et al. (Applied Environmental Microbiology, 1982).

- 17. Claim 52 depends directly on the independent claim 30 but limits that the substrate converting enzyme must be from a cell free extract. Haynie et al. teach that his method will use microorganisms such as yeast and fungi that inherently produce and secrete cellulases to hydrolyzed cellulose to glucose (Haynie et al. page 6 lines 14-30 and Lee et al. page 883, Cellulose). However Haynie et al. does not teach the use of cellulases from a cell free extract. This is taught by Chang et al.
- 18. Chang teach that extracellular cellulases extracted from the yeast Volvariella volvacea were able to hydrolyze cellulose (Chang, page 443 Figures 1 and 2). A person of ordinary skill in the art would be motivated to use cell enzyme extracts instead of whole microorganisms after reading page 12, lines 22-39 of Haynie et al. These lines summarize the fermentation conditions of the mixed culture solution such as finding suitable media and carbon source for both microorganisms. They also teach the disadvantage of using a linked system, which requires an increase in fermentation time since each step in the method is performed sequentially not simultaneously. One of ordinary skill in the art would recognize that cell free enzyme extracts from Chang et al. works well in multiple media (see page 441, col 1, "Medium" and page 443, FIG 1) and across a wide pH range of 4-8 (see Fig 1 and 2, page 443). This same artesian would recognize that these are similar media used by Haynie et al. (page 14-15, "Fermentation Media"). It would have been obvious to someone skilled in the art that the addition of a

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cell free enzyme extract that hydrolyzes cellulose to glucose to a microbial culture that converts glucose to 1,3-PD. The fermentation process could be run simultaneously in a media that is optimized to the single microbial culture. The motivation is provided by Haynie et al. who documents the problems of using a mixed culture method. The reasonable expectation of success is provide by Change who shows that it is possible to hydrolyze cellulose to glucose using a cell free enzyme extract.

- 19. Claim 64, is rejected under 35 U.S.C. 103(a) as being unpatentable over Haynie et al. as applied to the claims above (see paragraph 4) and in view of Richard (Cornell Waste Management Institute, 1996).
- 20. Claims 64 list several types of plant residues suitable for the method in claim 30. These are plant residues from corn, wheat, rice, barley or a combination thereof.

  Haynie teach that corn steep liquor and barley malt (Richard page 9, lines 30-31) are a suitable cellulosic feedstock for their invention. However Haynie does not specifically teach the feedstocks listed in claim 6, but Richard teach that these plant residues, including barley malt, have similar levels of cellulose and as such are art defined equivalents for the hydrolysis of cellulose to glucose (see appropriate listing in Richard). Since glucose is a substrate that the method of Haynie et al. will use for the production of the 1,3-PD, it would have been obvious to someone skilled in the art to substitute any of these plant residues in claim 64 into the method of Haynie et al. for the production of 1,3-PD.

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21. Claim 65, is rejected under 35 U.S.C. 103(a) as being unpatentable over Haynie et al. as applied to the claims above (see paragraph 4) and in view of Michaels et al. (Acta Biotechnologica, 1981)

22. Claim 65 list several types of plant residues suitable for the method in claim 30. These are plant residues from cassava, sugarcane, and sugar beet or a combination thereof. Haynie teach that sugar beet molasses is a suitable cellulosic feedstock for their invention. However Haynie does not specifically teach the feedstocks listed in claim 6, but Michaels et al. teach that sugar beet molasses and the feedstocks of claim 65 are art defined equivalents for the hydrolysis of starch, sugar, and cellulose to glucose (see page 351, "Summary", page 352 Table 1 and page 353 Figure 1).

Glucose is the intermediate that the method of Haynie et al. will use for the production of the 1,3-PD. It would have been obvious to someone skilled in the art so substitute any of these plant residues in claim 65 into the method of Haynie et al. for the production of glucose and the subsequent conversion into 1,3-PD.

In summary no claims, as written, are allowed for this application against the prior art listed above.

23. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See Cameron et al and Colin et al. on Form 892.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thane Underdahl whose telephone number is (571) 272-9042. The examiner can normally be reached on Monday-Friday, 8:00 to 17:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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